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Biotechnology Notes

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Biotechnology Notes, a compilation of agency activities, news events, and upcoming meetings, is prepared for members of the U.S. Department of Agriculture's (USDA) Committee on Biotechnology in Agriculture (CBA) by USDA's Office of Agricultural Biotechnology (OAB).

INSIDE USDA

ABRAC TACKLES MAJOR ISSUES AT FIRST MEETING OF NEW YEAR

On January 10-12, USDA's Agricultural Biotechnology Research Advisory Committee (ABRAC), comprised of biotech experts from outside the Department, will discuss three important issues related to agricultural biotechnology. Foremost on the agenda will be a presentation by Charles Hess, Assistant Secretary for Science and Education, on the recommendations of a subcommittee of the Biotechnology Science Coordinating Committee (BSCC) concerning the scope of organisms covered in guidelines and regulations. The subcommittee on scope, which includes representatives from USDA, the Environmental Protection Agency, the Food and Drug Administration, and the National Institutes of Health, has been developing a method of evaluating and cataloguing organisms based on their risk to the environment. The recommendations of the subcommittee could affect existing and future biotech regulations and guidelines at all Federal agencies. Hess is scheduled to speak at 11 a.m., Jan. 10. Time will be allotted for public comment.

Another meeting highlight will be a summary of a recent survey conducted by North Carolina State University on the public's perceptions of biotechnology, specifically genetic engineering. Professor Thomas Hoban will present the findings at 2 p.m. on Jan. 11.

Finally, David MacKenzie, director of the National Biological Impact Assessment Program, will demonstrate how USDA is using artificial intelligence to facilitate compliance with guidelines and regulations.

Other featured speakers include representatives from the National Science Foundation, the National Research Council, the Agency for International Development, the U.S. Army, and USDA's Agricultural Research Service, Animal and Plant Health Inspection Service (APHIS), Forest Service, and Food Safety and Inspection Service.

The meeting will be in Room 104-A of the Administration Bldg., and begins at 9 a.m. For more information, call Alvin Young, ABRAC Executive Secretary, at 202-447-9165. Minutes of all ABRAC meetings are published and made available, free-of-charge, from the Office of Agricultural Biotechnology (OAB).

HESS ADDRESSES EUROPEAN COMMUNITY

Charles E. Hess, USDA Assistant Secretary for Science and Education, spoke on the future of agricultural biotechnology, December 13, in Brussels, Belgium before the U.S.-European Community High Tech Group. The Group meets twice yearly to discuss science and technology issues.

Hess called for more and better trained people in the agricultural sciences and the need to attract young people into the field. He also said public agricultural research institutions should be revitalized and reorganized with an eye to "interdisciplinary" research. New funding for research is also a high priority as well as expansion of technology transfer programs that would link public and private sector research institutions.

In light of the debates over bovine somatotropin, Hess advised against adding any regulatory criteria that are unscientific or subjective. He said to do so would discourage researchers and "bring the advancement of science and technology to a halt."

Both the U.S. and European delegations agreed to the need for increased public information about biotechnology to raise the level of public debate. They also agreed to establish a new U.S.-European Community bilateral discussion subgroup, under the auspices of the High Tech Group, to discuss biotechnology research issues. The subgroup would complement ongoing bilateral discussions on regulatory matters.

OAB AND AID SWAP VIEWS

Alvin Young, Director of the OAB and Hiram Lerew, the newly-appointed biotechnology specialist in the Office of the Science Advisor to the U.S. Agency for International Development (AID) met November 17 to discuss biotechnology programs. Lerew expressed interest in receiving the "USDA Guidelines for Research with Genetically Modified Organisms Outside Contained Facilities" and the handbook, Introduction to Field Testing as soon as they are published so AID can distribute them to investigators working on biotechnology.

Lerew administers the Program in Science and Technology Cooperation (PSTC), one of three AID programs funding international research projects on ag biotechnology. The program has an annual budget of about \$5 million and funds 50 projects a year. In FY 1990, about 30 of these grants will be awarded to U.S. investigators who will be working with counterparts in developing countries on ag biotechnology research. Proposals are due February 1, 1990 for FY 1991. For more information, call Lerew at 703-875-4444.

バイオテクノロジー

In case you don't read Japanese, the above characters spell "biotechnology," targeted by the Ministry of Trade and Investment as one of Japan's key new industries. Now that the first greenhouse tests have taken place in Japan in which virus resistant tomatoes were created using by rDNA techniques, the Japanese government is particularly interested in developing regulations for safe field testing.

To learn more about U.S. initiatives, the government invited Terry Medley, Director of the Biotechnology, Biologics, and Environmental Protection (BBEP) unit at USDA's APHIS and Ernest Jaworski, Director of Biological Sciences Research and Development at Monsanto Company, to speak at last November's BRAIN (Bio-Oriented Technology Research Advancement Institution) conference in Tsuda, Japan.

Medley's presentation, "The Regulation of rDNA Organisms in the Environment, a U.S. Perspective", focused on the coordinated framework for regulation of biotechnological products and the importance of public involvement. He said USDA has approved 50 field trials to date and that U.S. companies are moving into the commercialization stage with these products.

Jaworski spoke on "Plant and Animal Biotechnology -- Perspectives Within a Global Context." He said Monsanto expects to market herbicide-resistant soybeans and insect-resistant cotton in 1993-1994.

DOWN MEXICO WAY

The Director and several members of APHIS's BBEP unit met with Mexican officials last October to discuss the regulation of biotechnology in the United States and Mexico. The APHIS team explained its program for regulating genetically engineered plants and microorganisms; Mexican officials described that country's regulatory procedures for field releases. If requested, the U.S. team said it would assist Mexican regulatory officials in reviewing applications submitted by U.S. companies.

BRINGING BIOTECH TO DEVELOPING NATIONS

Twenty-five representatives from 12 countries met in Vienna, Austria, December 18-19, to discuss how to ensure the safety of biotechnology applications in developing countries. The workshop was the fourth meeting of the United Nations Industrial Development Organization, the World Health Organization, and the United Nations Environment Program. Val Giddings, senior staff geneticist with APHIS's BBEP unit, participated in the meeting.

The group decided to draft general guidelines for discussion at its next meeting scheduled for early 1991. To learn more about the meeting or the sponsoring organizations, write to Joseph L. Zelibor, UNIDO, Vienna International Center, P.O. Box 300, A-1400, Vienna, Austria; or call 211-31-5351. The FAX number is 222-230-7355.

NEWS AROUND THE COUNTRY (AND THE WORLD)

BIOTECHNOLOGY AND THE CASSAVA PLANT

Known as the poor man's crop, cassava is consumed by about 700 million people, located mostly in Africa, Asia, and Latin America. Some African nations rely for more than 70% of calorie intake on cassava. The crop, however, is in trouble because of viral diseases, pests, cyanide toxicity, and decreased nutritional value due to pro-

cessing. As reported in the pilot issue of Monitor Biotechnology and Development, researchers around the world are using biotechnology to tackle these problems.

A few of the projects include research at Louisiana State University to increase the nutritive value of cassava by inserting synthetic genes to produce more nutritious proteins. At the University of Newcastle in Great Britain, scientists are studying possibilities for using genetic manipulation to prevent the production of cyanide in the roots of the crop. At Washington University, a scientist is working on a coat protein gene from the tobacco mosaic virus for transfer applications to two cassava viruses. Finally, work is underway at Plant Genetic Systems in Gent, Belgium on the possibility of engineering insect resistance by transferring Bacillus thuringiensis toxin genes into cassava.

Monitor Biotechnology and Development is a publication from The Netherlands. Subscription information may be obtained by writing to the Ministry of Foreign Affairs, DGIS DP0/OT, P.O. Box 20061, 2500 EB The Hague, The Netherlands.

MARKET FOR TRANSGENIC MICE OFF TO STRONG START

DuPont's transgenic mice seem to be a hit: Orders for 15,000 of the animals were filed before the company began its marketing campaign. The licensing arrangement calls for DuPont to recover some money from academic researchers and to retain more rights if the mice are used to develop significant commercial products. A market of \$25 to \$100 million is expected over the next few years.

STATE BIOTECH LAW SURVEY COMPLETED

A total of 22 state biotechnology laws were enacted in 1989, according to a survey just released by the Industrial Biotechnology Association (IBA). State Government Legislation on Biotechnology groups most of the laws into three categories: state-funded programs, DNA fingerprinting, and environmental release. To receive a copy, call the IBA at 202-857-0244.

BIOTECH AND THE ROAD AHEAD

Reflecting on biotechnology this decade and beyond, IBA president Richard Godown identified about a dozen issues/challenges facing the industry. One concerns patenting and a bill introduced into Congress that would limit the scope of transgenic animal patents. The IBA believes such a law "would be tantamount to no patent protection at all and would discourage investment in an area that promises to contribute greatly to agricultural advances in the future."

Another hot issue is public relations/perceptions. A company's success in marketing a biotech product, says Godown, rests in large part on the public's perception of and confidence in that product. The IBA will continue to work to educate the public as part of its long-term efforts to head off some groups that continue "to feed fears and misunderstanding of biotechnology."

Another challenge facing the industry is the decline in science education and literacy in this country. The result is a shortage of highly skilled personnel and, according to Godown, a decrease in the quality and quantity of industrial innovation.

IBA has made a special effort to prepare and produce many educational materials, including videos, for high school distribution.

COBIOTECH: INTERNATIONAL CHEERLEADERS FOR BIOTECHNOLOGY

The Committee for Biotechnology (COBIOTECH) is a scientific body of the International Council of Scientific Unions, a worldwide non-governmental scientific consortium of 20 international scientific unions, 75 national academies of science and councils of research, and 26 scientific associate organizations. COBIOTECH's goals are to promote biotechnology, with special concern for developing countries. Created in 1986, COBIOTECH's activities fall into three general areas: research, education, and information transfer. It sponsors workshops and conferences, conducts training courses, and prepares resource materials. To learn more about COBIOTECH, call Philip Gerhardt, past president, at 517-355-7530.

UP, UP AND AWAY

Tired of attending conferences held in the same old towns and cities year-in and year-out? Well then, have I got a meeting for you. The "First Asian Conference on Food Safety: Challenges of the 90's", will take place September 2-7, 1990, in Kuala Lumpur, Malaysia.

The conference is organized by the Malaysian Institute of Food Technology, the International Life Sciences Institute, the Malaysian Agricultural Research and Development Institute, and the Ministry of Health Malaysia, in cooperation with the Federation of the Institutes of Food Science and Technology in ASEAN, the Food and Agriculture Organization of the United Nations, and the International Union of Food Science and Technology.

The objectives of the conference are to focus attention on challenges of food safety in the Asian region, strengthen food control and infrastructure, provide a forum to discuss current and future issues in food safety, promote consumer awareness of food safety issues, and propose an action plan on food safety for the region for the 1990's. The technical program covers a broad range of topics including the application of biotechnology and irradiation to novel foods and processes, risk assessment and management, and harmonizing food regulations and trade.

For further information, call Lili Merritt at the International Life Sciences Institute in Washington, D.C., at 202-659-0074; the FAX number is 202-659-3859.

IN CASE YOU WEREN'T THERE

● Bacillus thuringiensis, transgenic fish, and bovine somatotropin were the topics of discussion at the Northeast Regional Workshop on Biotechnology, held September 25-27 in Falmouth, Mass., and sponsored by the Keystone Environmental, Citizen, State and Local Leadership Initiative for Biotechnology. Both Sally McCammon and Michael Lidsky, members of APHIS's BBEP staff, gave presentations. Representatives from Federal, industry, consumer, and environmental groups attended. Their primary interests centered on state regulation and sustainable agriculture.

- **Sixty scientists from 17 countries** gathered at the Institute of Forest Genetics in Placerville, Calif. last October to discuss woody plant biotechnology. The recent success of somatic embryogenesis from immature seed tissues in a number of conifers has created new enthusiasm for genetic engineering and clonal replication of important forest trees. The meeting was sponsored by the International Union of Forestry Research Organization Somatic Cell Genetics Working Party and co-sponsored by the NATO Advanced Research Workshop on Woody Plant Biotechnology. The proceedings will be published in late 1990.

- **At USDA's Annual Agricultural Outlook Conference** last November, OAB Director Alvin Young gave a presentation on "The Status of Biotechnology." He stressed four points: 1) The widespread effects of biotechnology in nearly all sectors of agriculture, including the food and fiber processing industries; 2) The impact of biotechnology applications on risks; 3) The impact of public understanding on the commercial success of biotechnology products; and 4) The need to ensure product safety standards are grounded in science, not politics. Young further explained the purpose of USDA's new research guidelines for outdoor field testing, which are now in the final stage of development.

Other panelists at the biotechnology session included IBA president Richard Goudon, who gave the industry perspective on biotechnology; and Jeffrey Innen, discussing intellectual property rights. The panel moderator was Terry Medley, Director of APHIS's BBEP unit.

The Outlook 1990 conference proceedings (order #AGES 9002) will be available in early 1990. Proceedings include all texts submitted by speakers and panelists plus transcripts of plenary sessions. The cost is \$20 a copy. To place an order, call 1-800-999-6779.

- **"Biotechnology: Science, Education and Commercialization"** was the title of an international symposium, December 3-6, in Gainesville, Fla. Sponsors included the University of Florida and USDA's OAB. About 150 people attended. The program centered on scientific advances, commercialization issues, international initiatives, education, and progress reports on the human genome project. Robb Fraley, director of plant science technology at Monsanto Company, gave an insightful talk on accomplishments in plant biotechnology, noting the impact of public perception on product acceptance. OAB Director Alvin Young spoke about the role of the Federal government in biotechnology research and regulation. Young also stressed the need for both academia and Federal agencies to communicate more effectively with the public about biotechnology issues. For information about receiving the meeting's proceedings, write to Indra Vasil, Graduate Research Professor, Institute of Food and Agricultural Sciences, University of Florida, Gainesville, Fla. 32608.

- **"Rationale and Description of Existing Regulations for the Release of Engineered Plants and Animals"** was the title of a talk given December 7 by Sally McCammon, a biotechnologist with APHIS's BBEP, at the Maryland Biotechnology Institute in Baltimore, Md. The conference was jointly sponsored by the United Nations International Development Organization and the Maryland Biotechnology Workshop for UN designates from Latin American countries including Bolivia, Brazil, Chile, Columbia, Costa Rica, Ecuador, Guatemala, Mexico, Peru, Uruguay, and Venezuela.

- **David R. MacKenzie**, Director of USDA's National Biological Impact Assessment Program, gave a presentation at an international symposium December 18 in Paris, France on "The Use of Artificial Intelligence to Facilitate Compliance with the U.S. Coordinated Framework for the Regulation of Biotechnology." The symposium was titled "The Biotechnologies from the Laboratory to the Field: What are the Implications

for Seeds?" The conference was sponsored by the French Ministry of Agriculture and Forestry and was well attended by European plant scientists from both the public and private sectors.

● **The Biotechnology Science Coordinating Committee (BSCC)**, at a meeting open to the public, met December 21 at the National Science Foundation (NSF) in Washington, D.C. Committee chairman John Moore, NSF, noted that the BSCC started 4 years ago to ensure biotechnology regulations were consistent among the top Federal agencies. Representatives from USDA, the Environmental Protection Agency, and the Food and Drug Administration updated members and the public on their biotech activities. David Pritzker, from the Administrative Conference of the United States, recommended a continuation of interagency coordination under the auspices of the Office of Science and Technology Policy (OSTP). He said the Conference also recommended that the President and the Congress, through the OSTP and the Office of Technology Assessment, survey biotechnology developments and agency regulation of biotechnology under existing statutes to see if current laws and regulations adequately protect public and private interests, or if there are any cases in which current regulation is unnecessary.

The Pharmaceutical Manufacturers Association said it supported the oversight and coordinating role of the BSCC. The IBA urged the BSCC to focus more on the development of data bases, agency cooperation on risk assessment, and public communication and less on regulatory policy. The Ecological Society of America recommended the BSCC do more to highlight scientific issues and principles to achieve "harmony in policy" among agencies.

The Environmental Defense Fund (EDF) said "BSCC meetings will potentially play an important role in agency decision-making" and "strongly urged that the BSCC continue to hold public meetings and invite public comment, as it has for the December 21 meeting." The EDF also asked the BSCC to prepare detailed minutes of each of its meetings. The EDF called Federal regulatory policy for biotechnology a "mishmash" that confuses academic researchers, and called for a uniform scope for the regulation of releases. The National Wildlife Federation suggested the BSCC has not held to its charter and should be "dissolved" and replaced by a new body that "provides opportunities for public participation."

NEW PUBLICATIONS

- "Emerging Biotechnologies in Agriculture: Issues and Policies." Progress Report VIII. November 1989. Prepared by the Committee on Biotechnology of the National Association of State Universities and Land-Grant Colleges. To receive a copy, call the Florida Agricultural Experiment Station at 904-392-1784.
- "Proceedings of the USDA/EPA/FDA Transgenic Plant Conference." Held in Annapolis, Md. September 7-9, 1988. To order a copy, call the Keystone Center at 303-468-5822.
- "Biodiversity and Biotechnology," an article by Kathryn George, Washington University, in Journal of Agricultural Ethics, Vol. 1, Number 3, 1988. pp. 175-192.

UPCOMING MEETINGS

Jan. 10-12: Meeting of USDA's Agricultural Biotechnology Research Advisory Committee (ABRAC). Agenda items include guidelines for researchers, biotech research needs and priorities, and the status of USDA's biotech activities. The meeting takes place at USDA, Room 104-A, Administration Bldg., 14th and Independence Ave., S.W., Washington, D.C. 20250. The hours are 9 a.m. to 5 p.m. Jan. 10 and 11 and 9 a.m. to 1 p.m. Jan. 12. For details, call Alvin Young, ABRAC Executive Secretary, at 202-447-9165.

Jan. 16-18: Sixth International Symposium on Separation Science and Biotechnology at the Bahia Mar in Ft. Lauderdale, Fla. Call 301-898-3772.

Jan. 17-19: Fifth Annual MIT Symposium: Biotechnology Process Engineering. Cambridge, Mass. Call 617-253-0805.

Feb. 14-20: Annual Meeting of the American Association for the Advancement of Science. New Orleans, La. Call 202-326-6448.

Feb. 26-Mar. 2: First European-Australian Bioindustry Meeting. Melbourne, Australia. For more information, write to N. Rau, RauCon, P.O.B. 1069, D-6912 Dielheim, F.R.G.

March 7-8: "Safe and Healthy Eating: New Policies to Restore Public Confidence" Sponsored by Public Voice for Food and Health Policy in cooperation with the National Food Processors Association. Call 202-659-5930.

March 11-14: "Trends in Biotechnology." Stockholm, Sweden. Sponsored by the Swedish Council for Forestry and Agricultural Research and the Swedish rDNA Advisory Committee. For details, write to the Swedish Council for Forestry and Agricultural Research, Odengatan 61, S-113 22 Stockholm, Sweden; or call 46-8-7360910. The FAX number is 46-8-332915.

Biotechnology Notes is written and edited by Marti Asner, a public affairs specialist with USDA's Office of Agricultural Biotechnology. Suggestions for items to include in future issues are always appreciated and may be sent to USDA/OAB, Room 321-A, Administration Bldg., 14th and Independence Ave., S.W., Washington, D.C. 20250; or call 202-447-9165. The FAX number is 202-447-8987.